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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IMCLONE SYSTEMS INCORPORATED,

Plaintiff,

against

MERCK KGaA,

Defendant.

05 CV 7724 (LAP) (AJP)

[ECF CASE]

COMPLAINT

Plaintiff ImClone Systems Incorporated ("ImClone"), by and through its undersigned attorneys, alleges for its Complaint herein against defendant Merck KGaA ("Merck"), on personal knowledge as to matters relating to itself and on information and belief as to other matters, as follows:

NATURE OF THIS ACTION

1. The underlying dispute between the parties to this lawsuit arises out of an agreement between the two signed in 1998. In the first three claims for relief set forth below (Counts I-III), ImClone seeks exclusively equitable or injunctive relief to clarify and protect its rights under that agreement. Because of the declaratory nature of the relief sought, ImClone requests expedited judicial resolution of these Counts pursuant to Fed. R. Civ. P. 57. The last two claims for relief set forth below (Counts IV and V) arise from the fact that, earlier, the parties created a separate mechanism to resolve certain issues through expedited arbitration, but after agreeing in writing to that mechanism Merck asserted that the arbitration agreement was

rendered invalid by its successful objection to one and then another arbitrator agreed to by the parties, ultimately refusing to proceed with expedited arbitration altogether. Counts IV and V seek determinations that Merck either did not have, or in the alternative if it had it has forfeited, any right to seek arbitration.

PARTIES

2. Plaintiff ImClone is a Delaware corporation with its principal place of business in New York, NY.

3. Defendant Merck is a German corporation with its principal place of business in Darmstadt, Germany.

JURISDICTION AND VENUE

4. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C § 1332(a)(2) because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00, exclusive of costs and interests.

5. Venue in this judicial district is proper under 28 U.S.C. § 1391(a)(2) and (a)(3) in that a substantial part of the events or omissions giving rise to the claim occurred in this district, and defendant Merck is subject to personal jurisdiction in this district.

BACKGROUND

6. On December 14, 1998, ImClone entered into a Development and License Agreement ("Agreement") with Merck, the general purpose of which was to give Merck the right to commercialize and market a product candidate known as "C225" outside of the United States and Canada.

7. C225 is a monoclonal antibody that targets and thereby inhibits Epidermal Growth Factor Receptors ("EGFr") that was then under development by ImClone. The Agreement defines the term "Compound" as C225.

8. The "C" in C225 denotes that it is a "chimeric" monoclonal antibody, that is, an antibody originally derived from mice and that still contains a significant portion of mouse antibody, including in particular the "complementarity determining region" or "CDR", the portion that defines what type of cells the antibody targets.

9. More specifically, the Agreement grants Merck the exclusive right to make, use and sell "Licensed Products" and "Alternative Products" in the relevant geographic areas.

10. "Licensed Products" is defined to include the compound C225 and "all products incorporating the Compound and any and all products made by use of any compound or product covered by any Licensed Product Patent, including, but not limited to, any Improvements to the Compound". Agreement § 1.21.

11. "Licensed Product Patents" is defined to include all non-U.S. and non-Canadian patents or patent applications "covering the Compound and/or any Improvement and/or process for the manufacture or use of the Compound and/or such Improvement, including but not limited to, those set forth in Schedule B". Agreement § 1.20.

12. "Improvements" is defined as "all enhancements ImClone or any of its Affiliates may make to the Compound prior to the termination of this Agreement, whether or not patentable, which are invented, developed, discovered or otherwise acquired by ImClone or any of its Affiliates". Agreement § 1.19.

13. "Alternative Products" is defined as "those products which, as part of the Research and Development, may be developed and/or acquired subsequent to the execution of this Agreement solely by ImClone or any of its Affiliates or jointly with Merck or any of its Affiliates as an alternative to the Compound, including but not limited to any inhibitors of EGFr or improvements thereto that are not the Compound or an Improvement". Agreement § 1.4.

14. "Research and Development" is defined as "that work which ImClone and Merck undertake to conduct in connection with Licensed products, and, to the extent applicable, Alternative Products, as set forth in the Research and Development Protocol". Agreement § 1.34.

15. "Research and Development Protocol" is defined as "the plan for the conduct of the Research and Development during the period of Research and Development, as set forth in *Schedule D*, attached hereto and specifically incorporated herein, and as may be amended by the parties from time to time". Agreement § 1.35.

16. The Agreement also provides for resolution of disputes by arbitration before a three-person panel, except that the arbitration provision "shall not be construed to preclude any action for an injunction or other equitable relief before any court of competent jurisdiction". Agreement § 13.1.

17. The Agreement also provides that it "shall be governed by and construed in accordance with the laws of the State of New York without regard to the conflict-of-laws rules of such State." Agreement § 16.2.

18. After the Agreement was executed, ImClone on its own and with no support from Merck developed a new and different monoclonal antibody that also targets and inhibits EGFr, known as 11F8. 11F8 is derived entirely from human antibodies, and includes no portion derived from or based upon any mouse antibody (including C225). The CDR of 11F8 is entirely different from that of C225.

19. ImClone's work on 11F8 was never discussed with Merck and was never made a part of the parties' joint Research and Development or included in the Research and Development Protocol. Indeed, during the course of their relationship, the parties never even

discussed the possibility of jointly investigating or exploring potential alternatives to C225. The Agreement contains no restriction on independent work by either party on such products; in fact, since even before the Agreement was signed Merck has been working on its own independent monoclonal antibody that targets and inhibits EGFr, a compound known by Merck as "EMD 72000".

20. In 2003, ImClone began actively seeking a partner to develop, manufacture, commercialize and market 11F8 in exchange for the rights to distribute the product outside the United States and Canada. Among other companies, ImClone approached Merck as a potential partner. Although Merck initially expressed some interest in entering into an agreement for the new product, in mid-2004 it asserted that 11F8 was covered by the Agreement and that Merck therefore already held the exclusive right to make, use or sell 11F8 in the relevant geographic area.

21. ImClone denies that 11F8 is covered by the Agreement or that Merck has any rights to 11F8. Nevertheless, Merck's claim of rights to 11F8 has hindered and interfered with ImClone's efforts to locate a partner to work with to commercialize 11F8.

22. Merck's improper assertion of rights in 11F8 has wholly impeded ImClone's efforts regarding 11F8, and has infringed upon ImClone's clear and unequivocal title therein.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of ImClone's Rights to 11F8)

23. ImClone repeats and reavers the allegations of paragraphs 1 through 22 as if fully set forth herein.

24. This Claim for Relief seeks only equitable relief.

25. Merck claims some rights, title, or interest in 11F8 under the Agreement.

26. ImClone denies that 11F8 is covered by the Agreement or that Merck has any rights to 11F8.

27. ImClone asserts that 11F8 is not governed by the Agreement, and that all such claims which Merck may exact as to 11F8 under the Agreement or otherwise are invalid and of no force and effect.

28. Merck's claim of rights to 11F8 has hindered and interfered with ImClone's efforts to locate a partner to work with to commercialize 11F8.

29. Accordingly, an actual case or controversy exists among the parties.

30. By reason of the foregoing, ImClone is entitled to a judicial declaration that 11F8 is not covered by the Agreement, and that ImClone has the sole and exclusive right to develop, manufacture, commercialize, and market 11F8.

31. A judicial determination of the rights and obligations of the parties is necessary in order to avoid further impairment of ImClone's rights and to prevent further delay in the development and commercialization of 11F8 as an anticancer treatment.

SECOND CLAIM FOR RELIEF
(Quiet Title)

32. ImClone repeats and reavers the allegations of paragraphs 1 through 31 as if fully set forth herein.

33. This Claim for Relief seeks only equitable relief.

34. Merck claims that 11F8 is covered under the Agreement, and that it has some rights, title, or interest therein.

35. ImClone alleges that all such claims which Merck may assert as to 11F8 are invalid and of no force and effect and that ImClone is seized and possessed of absolute and

unencumbered title to 11F8, free of any claim of interest therein by Merck or its agents, attorneys, employees, affiliates, or assigns.

36. By reason of the foregoing, ImClone is entitled to a judgment finally and conclusively determining that Plaintiff is the lawful owner and is vested with absolute and unencumbered title and rights to 11F8.

THIRD CLAIM FOR RELIEF
(Permanent Prohibitory Injunction)

37. ImClone repeats and reavers the allegations of paragraphs 1 through 36 as if fully set forth herein.

38. This Claim for Relief seeks only injunctive relief.

39. ImClone's interest in and ability to develop, manufacture, commercialize and market 11F8 has and will continue to be irreparably injured unless Merck is permanently enjoined from interfering with same by asserting that 11F8 is covered under the Agreement or that it has any right, title, or interest therein.

40. Based upon the foregoing, Plaintiff is entitled to entry of a permanent injunction prohibiting Merck from asserting that 11F8 is covered under the Agreement or that it has any right, title, or interest therein, or otherwise acting or failing to act in any way that could interfere with Plaintiff's absolute and unencumbered title in 11F8.

41. Plaintiff has no adequate remedy at law or otherwise.

FOURTH CLAIM FOR RELIEF
(Declaratory Judgment that this Dispute Should Be Litigated Due to the Failure of the Terms of Reference)

42. ImClone repeats and reavers the allegations of paragraphs 1 through 41 as if fully set forth herein.

43. When the dispute over 11F8 arose, both parties recognized that the critical commercial need for an expedited resolution, quicker than either litigation or, to the extent the issue was covered by § 13.1, arbitration as provided for therein. To achieve that goal, the parties agreed to resolve this dispute by a streamlined and expedited binding arbitration process before a single neutral arbitrator. To memorialize and formalize that agreement, the parties negotiated the "Terms of Reference And Procedures for Arbitration" ("Terms of Reference").

44. At the same time they were negotiating the provisions of the Terms of Reference, the parties sought to agree on a neutral arbitrator. Merck proposed Arthur J. England, Jr. and the parties each conducted due diligence and interviewed Mr. England, then accepted him as the arbitrator.

45. The Terms of Reference were signed by both parties as of April 13, 2005. That document memorialized the parties' amendment of the Agreement to resolve the 11F8 dispute through expedited arbitration, appointed Mr. England to hear the matter, and set forth the schedule and procedures to be followed leading up to the hearing to begin on August 1, 2005.

46. Following the execution of the Terms of Reference, the parties proceeded with discovery and preparation for the August 1 hearing as called for by the Terms until May 11, when Merck notified ImClone that it objected to the continued participation of England as arbitrator, as the result of a perceived conflict of interest. Subsequently, at Merck's insistence, England withdrew as arbitrator for the 11F8 dispute.

47. Although the parties continued to engage in discovery and follow the procedures set forth in the Terms of Reference even after England's withdrawal, Merck subsequently asserted that that "Mr. England's appointment to be the sole arbitrator . . . was a material

provision of the Terms [of Reference] and his subsequent recusal and inability to perform that role invalidates the Terms".

48. By the Terms of Reference the parties committed to resolve the 11F8 dispute through an expedited arbitration procedure before a single neutral arbitrator.

49. Thus, as the Terms of Reference expressly provide, to the extent that any portion of the 11F8 dispute might previously have been deemed to be subject to the arbitration procedures of § 13.1, that provision is no longer applicable to this dispute and the Terms of Reference is only effective agreement concerning the resolution of this matter.

50. If Merck is correct that because England is no longer able to serve as arbitrator the Terms of Reference are invalid, then the parties are no longer bound to resolve this dispute pursuant to the Agreement *or* the Terms of Reference, and are then free to do so before this Court.

51. By reason of the foregoing, ImClone is entitled to a judicial declaration that the Terms of Reference are no longer binding, that the Agreement does not control resolution of the 11F8 dispute, and that the parties are free to resolve the 11F8 dispute in this Court.

FIFTH CLAIM FOR RELIEF
(Declaratory Judgment that this Dispute Should Be Litigated Because Merck Has Repudiated the Terms of Reference)

52. ImClone repeats and reavers the allegations of paragraphs 1 through 51 as if fully set forth herein.

53. Subsequent to England's recusal as arbitrator, on May 25, 2005, Merck, through its counsel, Kevin Toner ("Toner") of Heller Ehrman ("Heller") proposed Gerald Aksen to replace England as arbitrator. That same afternoon, Toner and ImClone's counsel, Colin Underwood ("Underwood") of Proskauer Rose LLP ("Proskauer"), contacted Aksen concerning his availability and interest in serving in this matter. During that telephone call, Toner explained

that the Terms of Reference called for a hearing beginning on August 1, 2005, and that it was important that a replacement arbitrator be able to keep that date. Mr. Aksen replied that he was available at that time and that he had no conflicts with either party.

54. On May 26, 2005, Underwood informed Toner that ImClone was willing to appoint Mr. Aksen as the replacement arbitrator. The following day, Toner, via email, replied that Merck also agreed to use Mr. Aksen, subject only to a conflicts review. Toner clarified this acceptance, with the same condition, via email, on June 2.

55. Upon receiving clarification from Toner, Underwood left a message for Toner attempting to schedule a telephone conference to notify Mr. Aksen of the parties' agreement to appoint him, or requesting Merck's authority to notify Mr. Aksen unilaterally of the parties' acceptance. Toner responded that afternoon with an email granting Underwood Merck's permission to convey the parties' acceptance to Mr. Aksen. Underwood promptly telephoned Mr. Aksen to inform him of his appointment, and followed that telephone call with an e-mail, copied to Toner, confirming that "both ImClone and Merck have agreed to retain [Aksen] to arbitrate our dispute."

56. On June 6, Mr. Aksen sent an e-mail to both parties accepting their appointment. That e-mail stated as follows:

> Thank you for your June 2 e-mail appointing me as arbitrator in the above matter. I am available all day today (June 6) and tomorrow (except from 11:00 am to 12:30 pm) for a telephone conference to discuss the further planning and scheduling of the case. (I have already penciled in the first week of August for hearings pursuant to our previous conference.)

57. Pursuant to Mr. Aksen's request, Underwood and Toner spoke with Mr. Aksen by telephone on June 7, 2005. During that call, Aksen explained that he did not need any formal retention agreement, and that his general practice was to send a letter to counsel confirming his retention and to ask the parties for a retainer. Both Underwood and Toner agreed with that

approach. Counsel then discussed the schedule the parties had agreed to for the hearing and agreed to send Aksen each party's preliminary statement and a copy of the Terms of Reference that governed the arbitration. Toner also proposed that each party provide Mr. Aksen with an *ex parte* list of their potential witnesses, in advance of the June 18 date provided by the Terms of Reference, so that Mr. Aksen could ensure that he had no conflicts with anyone either party expected to call as a witness at the hearing.

58. Mr. Aksen followed up the June 7, 2005 conversation with a letter dated June 8, 2005, writing:

> This will confirm that your clients ImClone and Merck have jointly agreed that the undersigned be appointed as the sole neutral arbitrator in a pending dispute arising out of a December 14, 1998 license-development agreement. By this letter, the undersigned consent to serve in that capacity.

The letter also set forth Mr. Aksen's understanding of the materials the parties would be supplying, and explained the payment arrangements, including a retainer from each party based on the anticipated length of the hearing.

59. After receiving Mr. Aksen's letter, on June 9 ImClone counsel provided Aksen with an *ex parte* list of the potential witnesses that ImClone might call to testify at the hearing. By return e-mail on June 10, Mr. Aksen confirmed that he had no conflict with any of the individuals ImClone had identified.

60. On June 30, Underwood forwarded to Mr. Aksen ImClone's share of the initial retainer requested by Mr. Aksen in his June 7 letter, along with a signed copy of that letter indicating ImClone's agreement to the payment arrangements proposed by Mr. Aksen.

61. Upon information and belief, Merck also complied with Mr. Aksen's June 7 letter by sending him an *ex parte* list of its potential witnesses to testify at the hearing. Upon

information and belief, Mr. Aksen had no conflict with any of the individuals Merck had identified.

62. Upon information and belief, Merck did not pay Mr. Aksen its share of the initial retainer requested in his June 7 letter and did not sign that letter to indicate Merck's acceptance of the payment terms proposed therein.

63. In the meantime, the parties continued with discovery and preparation for the August 1 hearing. From the time that Merck insisted that Mr. England withdraw as arbitrator, the parties exchanged documents and discovery responses, Merck asked for and obtained a document that it claimed had been inadvertently produced to ImClone, and on June 23 took the deposition of Michael Howerton, ImClone's CFO. The parties also scheduled the deposition of three Merck witnesses in Germany and ImClone was preparing for those depositions to be held on July 6 and 7, when at the last minute, on the afternoon of Monday July 4, after ImClone's counsel had spent the July 4th weekend preparing for the depositions and less than a day before they were planning to depart for Germany, Merck cancelled all of the depositions without explanation.

64. Instead of proposing new dates for the depositions, Merck replaced Heller with new counsel, Kelley, Drye & Warren LLP ("Kelley Drye"). By letter dated July 7, 2005, Kelley Drye informed Proskauer of the counsel substitution, and that it was appearing on Merck's behalf in this matter. As noted above, in that same letter, for the first time, and contrary to its prior course of conduct, Merck took the position that its disqualification of Mr. England had invalidated the Terms of Reference.

65. Since July 7, Merck has repeatedly stated its position that the Terms of Reference is no longer valid, and has continued to repudiate the Terms of Reference by failing to abide by the provisions and requirements set forth therein.

66. In telephone calls, meetings and correspondence, Merck's new counsel has repeatedly sought to negotiate a new arbitration agreement for the 11F8 dispute with terms that are inconsistent with the Terms of Reference.

67. By letter of August 22, 2005, Merck's new counsel advised ImClone that if ImClone is unwilling to accept the terms of Merck's new proposal, the only alternative is arbitration pursuant to § 13.1 of the Agreement.

68. Merck has waived any right to arbitrate this dispute pursuant to the Terms of Reference by repudiating and abandoning that agreement. Merck's repudiation and abandonment of the Terms of Reference discharges ImClone from any obligations thereunder.

69. Because the parties removed the 11F8 dispute from the purview of the Agreement by opting for an expedited arbitration mechanism as memorialized in the Terms of Reference, and because Merck has since repudiated and abandoned the Terms of Reference, the parties are no longer bound to resolve this dispute pursuant to the Agreement *or* the Terms of Reference.

70. By reason of the foregoing, ImClone is entitled to a judicial declaration that the Terms of Reference are no longer binding on the parties, that the Agreement does not govern resolution of the 11F8 dispute, and that the parties are free to resolve the 11F8 dispute in this Court.

PRAYER FOR RELIEF

WHEREFORE, plaintiff ImClone prays:

1. On the First Claim for Relief, as part of the equitable and injunctive relief sought herein, that this Court declare that that 11F8 is not covered by the Agreement and that ImClone has the sole and exclusive right to develop, manufacture, commercialize, and market 11F8;

2. On the Second Claim for Relief, that this Court finally and conclusively determine that ImClone is the lawful owner and is vested with absolute and unencumbered title and rights to 11F8;

3. On the Third Claim for Relief, that this Court enter an injunction prohibiting Merck from asserting that 11F8 is covered under the Agreement or that it has any right, title, or interest therein, or otherwise acting or failing to act in any way that could interfere with Plaintiff's absolute and unencumbered title in 11F8;

4. On the Fourth and Fifth Claims for Relief, that this Court declare:

   a. that the Agreement does not control resolution of the 11F8 dispute;

   b. that the Terms of Reference are no longer binding on the parties; and

   c. that the parties are free to resolve the 11F8 dispute in this Court, or by any other mechanism they see fit to employ; or

5. For such other and further relief as the Court deems just and proper.

Dated: New York, New York
September 1, 2005

/s/ Louis M. Solomon

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